

K101253

**SPECIAL 510(K) SUMMARY**

JUN 29 2010

This summary of Special 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is:

**1. Submitter's Identification:**

Radiant Innovation Inc.,  
1F, No.3 Industrial E. 9<sup>th</sup> Rd., Science-Based  
Industrial Park, HsinChu, Taiwan

**Contact:**

Mr. James Huang  
QA Department Manager  
Radiant Innovation Inc.  
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Date Summary Prepared: Jun/21/2010

**2. Name of the Device:**

Infrared Ear Thermometer TH60N  
Classification Name: Thermometer, Electronic, Clinical  
Regulation Number: 21 CFR 880.2910

**3. Current Clearance Device:**

Radiant Innovation Infrared Ear Thermometer, Models TH01BN (510(k)#: K070976), TH5XY series (510(k)#: K063185), TH00XY series (510(k)#: K051269), THXXN series (510(k)#: K040377), TH1 series (510(k)#: K030324), TH88 series (510(k)#: K020504) and TH8 series (510(k)#: K011059).

**4. Device Description:**

The Radiant Innovation Inc., Infrared Ear Thermometer, Model TH60N is electronic thermometer using an infrared detector (thermopile detector) to detect body temperature from the auditory canal. Its operation is based on measuring the natural thermal radiation emanating from the tympanic membrane and the adjacent

surfaces of the patient.

To measure ear temperature, the ear thermometer is inserted into a patient's outer ear canal. A start button is pressed to start the measurement through the radiation exchanges. The electrical signal read out from the detector is fed to the circuit for amplification and calculation. The measured temperature then appears on a LCD display. The total operation takes a few seconds.

5. **Intended Use:**

The device is an electronic clinical thermometer using an infrared sensor to detect body temperature from the auditory canal in the neonatal, pediatric and adult population used in the home setting.

6. **Technological Characteristics:**

Radiant Infrared Ear Thermometer TH60N is an ear thermometer without probe cover with some sub-functions such as: temperature unit switchable, recall memory, scan function, last reading display, ambient temperature, and backlight.

And, the model number will indicate backlight is with or not.

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Compliance to applicable voluntary standards includes ASTM E1965-98 and EN12470-5:2003, as well as EN 60601-1 (IEC 60601-1) and EN 60601-1-2 (IEC 60601-1-2) requirements.

Guidance Documents included the FDA "Guidance On The Content of Premarket Notification (510(k)) Submissions for Clinical Electronic Thermometers", "How to Prepare A Special 510(k)", "Deciding When to Submit a 510(k) for a Change to an Existing Device".

8. **Conclusions:**

The RII Infrared Ear Thermometer TH60N, have the same intended use and similar characteristics as the cleared device TH01BN. Moreover, bench testing contained in this submission supplied demonstrate that the modification of TH60N do not raise any new questions of safety or effectiveness. Thus, the RII Infrared Ear Thermometer, Model TH60N is substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 29 2010

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -WO66-G609  
Silver Spring, MD 20993-0002

Mr. James Huang  
Quality Assurance Department Manager  
Radiant Innovation Incorporated  
1F, Number 3 Industrial East 9<sup>th</sup> Road, Science-Based  
Industrial Park, HsinChu, Taiwan

Re: K101253

Trade/Device Name: Radiant Innovation Incorporated Infrared Ear Thermometer  
TH60N  
Regulation Number: 21 CFR 880.2910  
Regulation Name: Clinical Electronic Thermometer  
Regulatory Class: II  
Product Code: FLL  
Dated: June 21, 2010  
Received: June 24, 2010

Dear Mr. Huang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

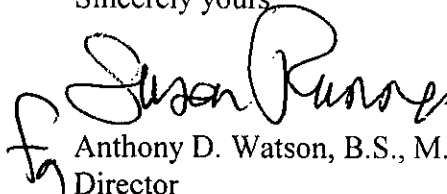
<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Anthony D. Watson", is written over the typed name.

Anthony D. Watson, B.S., M.S., M.B.A.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

EXHIBIT # B

INDICATIONS FOR USE

510(k) Number (if known): K101253

Device Name: Radiant Innovation Inc. Infrared Ear Thermometer TH60N

Indications For Use:

The device is an electronic clinical thermometer using an infrared sensor to detect body temperature from the auditory canal in the neonatal, pediatric and adult population used in the home setting.

Prescription Use \_\_\_\_\_ AND/OR Over-The-Counter Use ☒  
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF  
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

*for ABC Chapman*  
(Division Sign-Off)

Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

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